

SUBJECT:

EXCHANGE OF LETTERS

Importation of
Puffer Fish -
Allowable On
Certain Conditions

Between

JAPAN AND THE U.S. FOOD AND DRUG ADMINISTRATION

REGARDING PUFFER FISH

Import Conditions for Japanese Puffer Fish

Notes:

The FDA contact
for this MOU is
Phil Spiller, HFS-
400

Tel. No.
202-418-3133

This EOL is in
effect indefinitely.

Introduction:

Puffer fish has been on FDA's Automatic Detention List since 1980, because the product "...appears to contain the poisonous and deleterious substance tetrodotoxin." FDA's certification program requires the agency to audit sample proposed entries. FDA's concerns prior to the decision to allow the importation of Japanese puffer into the United States, were associated with the sampling of puffer fish and the analytical methodology to determine the absence of tetrodotoxin. For puffer fish there is no adequate sampling scheme that can assure a safe lot, since any single fish may contain a lethal dose of the toxin. While progress has been made in analytical methodology to determine the presence of toxin, it is still inadequate. These concerns are compounded by the fact there is no known antidote for tetrodotoxin.

The four years of discussions between the FDA and the Japanese Ministry of Health and Welfare (MHW) officials were concerned with the actions the Japanese government would take to assure that FDA's concerns would be adequately addressed, thus ensuring the safety of imported puffer fish.

Action Taken:

Both parties discussed and agreed to an intention to permit the import of Japanese puffer fish on the basis of "special occasions". provided that following actions were taken:

- I. Each entry is to be inspected by the appropriate official of the Japanese government and certified as safe.
- II. Develop and implement the necessary conditions (Proposed Requisite Matters) for export of Japanese puffer fish into the United States.

Notes:

(a) Specific Criteria

1. Species and Regions (edible parts)
2. Processing (hygienic Practices)
3. Packing
4. Labeling
5. Transportation
6. Certification (Department of Health of the city of Shimonoseki)

(b) Other Matters

1. There is to be a recognized export organization
 - Shimonoseki Fugu Export Association, Shimonoseki city, Yamaguchi, Japan
2. There is to be a recognized import organization
 - Wako International Corporation, NY, NY
 - Torafugu Inspection Board
 - Torafugu Buyer's Association (conditions of membership)

Conclusion:

The agreement was never established to permit the unrestricted importation of Japanese puffer fish into the United States. Rather, both parties discussed and agreed to an intention to permit the import of Japanese puffer fish on the basis of "special occasions". The decision to allow the restricted importation of puffer fish were predicated on the Japanese Ministry of Health and Welfare (MHW) officials development and implementation of an export protocol for puffer fish, which would provide the assurance that FDA's concerns would be adequately addressed, thus ensuring the safety of imported puffer fish.

It is recommended that the current system of control (Restricted Entry and Automatic Detention) for the importation of Japanese puffer fish remain unchanged, for following reasons: (1) the likelihood for increasing the potential public health hazard associated with the consumption of puffer fish; and (2) the intention of the parties was never to allow puffer fish to be imported for general distribution, but only on the basis of special occasions.

Notes:

August 26, 1988

**First Secretary,
Health and Welfare
is currently Mr. Eiji
Habu**

Junichi Shiraishi
First Secretary
Health and Welfare
Embassy of Japan
2520 Massachusetts Avenue, N.W.
Washington, DC 20008

Dear Mr. Shiraishi:

All of us who were associated with the visit of Mr. Ito and Dr Yoshihira hope that their mission was successful and that they learned as much from us as we did from them. I Believe we all realize that the continuing exchange of ideas and viewpoints is very beneficial to both sides.

As you may recall, a portion of our discussions on Tuesday, August 23, 1988, concerned the status of the Japanese proposal to allow puffer fish or fugu into the United States. Unfortunately, we are not in a position to permit the unrestricted entry of puffer fish into the United States. We have carefully considered the [possibility of permitting the entry of puffer fish if each shipment is accompanied by a certificate attesting that each fish is free of the three toxins associated with fugu (Tetrodotoxin, 4-Epitetrotoxin, and Anhydrotetrotoxin) and they meet the other requirements of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. The Agency does not have the resources required to monitor such a certification program.

Two of the problems associated with a fugu certification program concern sampling and analytical methodology. All of our certification programs require FDA to audit sample proposed entries. For puffer fish there is no adequate sampling scheme that can assure a safe lot since any single fish may contain a lethal dose of toxin. While progress has been made in analytical methodology to determine the presence of the toxin, it is still inadequate. These problems are compounded by the fact that there is no known antidote for tetrodotoxin.

We will allow the entry of a limited number of puffer fish shipments for special occasions, provided that each entry is inspected by the appropriate official of the Japanese government and certified as safe. In addition, we must be advised in advance of each prospective shipment,

Notes:

including its expected arrival date and the intended port of entry through which the shipment will be entered. This information is to be provided to:

**Director,
Office of Seafood,
HFS-400
(Currently: Phil
Spiller)**

Director
Division of Regulatory Guidance, HFF-310
Center for Food Safety and Applied Nutrition
200 C Street, S.W.
Washington, DC 20204

**Tel. No.
(202) 418- 3133**

Telephone number (202) 485-0187

Please convey our decision to Dr. Ko Namba, Director, Veterinary Sanitation Division, Ministry of Health and Welfare. I trust you will continue to be a strong proponent of exporting quality Japanese food products to the United States.

Sincerely yours,

**CFSAN Director is
currently: Dr. Fred
Shank**

Richard J. Ronk
Acting Director
Center for Food Safety
and Applied Nutrition

Notes:

MINISTRY OF HEALTH AND WELFARE
1-2-2, Kasumigeseke, Chyoda-ku, Tokyo
100 JAPAN
Cable Address: KOSEISHO TOKYO

October 24, 1988

CFSAN Director is
currently: Dr. Fred
Shank

Dr. Richard J. Ronk
Acting Director,
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204
U. S. A.

Re: "Export of Japanese Puffer Fish to the U.S." Relative to August 26
letter from Dr. Ronk to Mr. Shiraishi, First Secretary, Health and
Welfare, Embassy of Japan

Dear Dr. Ronk:

This is to inform you that we are now understanding your basic stand
on the aforementioned matter.

We also appreciate your understanding of the safety and sanitation
factors about Japanese puffer fish as contained in the data and
comments which we have already sent to you.

I welcome and consent to "an intention to permit the import of
Japanese puffer fish, although on the basis of "special occasions" as
you have proposed.

I am enclosing a proposal on "Requisite Matter for the export of
Japanese Puffer Fish to the U.S." by the Japanese government.

As I have already informed you. I will be in Washington, D.C., on official
business in early November. I had been looking forward to meeting you
and to reaching final agreement on the matter in question, so I most
deeply regret that you will not be in town. Accordingly, I intend to
entrust the matter to Mr. Hisanori Uchiyama, Director of Food Chemistry
Division, who is participating in the Japan-U.S. Food Chemical Panel
Meeting which takes place in Washington, D.C. on November 9-10.

I am sure that you will find the contents of our proposal in conformity
with your position but if you feel otherwise, please inform us in advance
via Mr. Shiraishi.

Notes:

At this point, I would like to convey to you our most fervent desire to reach a final agreement on this matter at the earlier possible date. I feel most fortunate that I can collaborate with Dr. Ronk in opening a new page of historical significance in U.S.-Japan relations by introducing Japanese dietary culture.

Sincerely yours,

Ko Namba
Director,
Veterinary Sanitation Division
Environmental Health Bureau
Ministry of Health and Welfare

Notes:

Requisite Matters for Export of Japanese Puffer Fish to the U.S.

1. Species and Regions

Restricted to muscles, skins and testicles of Tiger puffer (Fugu rubripes rubripes) excised entirely of poisonous regions.

2. Processing (Excision of Poisonous Regions)

Appropriate processing will be undertaken by a certified person (puffer fish processing specialist) in accordance with a prefectural ordinance at a facility authorized by the governor of prefecture or the mayor of city establishing health center.

3. Packing Form

After processing, the puffer fish, in portions of 2-3 kg., is vacuum-packed in clean, sanitary synthetic resin film, followed by freezing by the rapid freezing method. After freezing, the puffer fish in portions of 10 kg. is placed in polystyrene foam containers with dry ice and sealed up.

4. Labeling for Product

The following items will be indicated in an easily seen place on the package containing the product container:

- (1) Description of product
- (2) Net weight
- (3) Catching sea area
- (4) Name and address of processing facility
- (5) Name of responsible person for processing
- (6) Date of processing

5. Transportation

Transportation (air transport) will be provided with temperature maintained at -18 degrees C (-0.4 degrees F).

6. Certificate

The governor of prefecture or the mayor of city establishing health center, based on an application from the person or juridical person who carries on a puffer fish processing, will undertake confirmation of paragraphs "1" and "2" by food sanitation inspector executing the authorities of the governor of prefecture or the mayor of city establishing health center. He will then issue a certificate as per attached form in lots (in terms of lots adopted at the processing facility according to those processed the same day) of the said product.

Notes:

7. Other Matters

- (1) The export organization (an organization, constituted a person or juridical person who carries on a puffer fish processing, set up for the purpose of exporting puffer fish to the U.S.) will undertake export 2-3 times a year between September and March of the following year.
- (2) In the execution of export, the export organization must forward the following statement of its export plan to the U.S. import organization (an organization set up by importers and restaurants for the purpose of sanitation control), and the import organization in turn must report this promptly to the FDA.
 - a. Description of product
 - b. Number of packages and net weight
 - c. Name and address of processing facility
 - d. Date of shipping
 - e. Name and address of exporter
 - f. Airport of shipment and flight number
 - g. Date of arrival
 - h. Name and address of importer
 - i. Airport of arrival and flight number
- (3) The importing organization, in cooperation with the FDA inspector, will inspect the cargo upon its arrival as to sanitary condition, etc., in order to ensure full sanitation. The importing organization is to retain the items of inspection and results thereof for one year.

NOTE: Under the Japanese Food Sanitation Law, portions of the authority of the Minister of Health and Welfare are entrusted to the governor of prefecture concerned (or the mayor having jurisdiction over the establishment of a health center). The authority to undertake inspection and guidance relative to business facilities concerned comes under such entrustment.

Notes:

**STANDARD FORM AUTHORIZED
BY THE MINISTRY OF HEALTH
AND WELFARE OF JAPAN**

SANITARY CERTIFICATE OF PUFFER FISH

No: _____

Date: _____

TO WHOM IT MAY CONCERN:

This is to certify that Japanese puffer fish for export to the United States has been completely excised of poisonous parts as follows in accordance with the Regulations governing _____.

- 1. Description of product**
- 2. Number of packages and net weight**
- 3. Catching sea area**
- 4. Name and address of processing facility**
- 5. Name of responsible person for processing**
- 6. Date of processing**
- 7. Name and address of shipper**
- 8. Name and address of consignee**

Signature (Name of Food Sanitation Inspector)

Official Title (Name of prefecture or city)

Notes:

December 6, 1988

Dr. Ko Namba
Director
Veterinary Sanitation Division
Environmental Health Bureau
Ministry of Health and Welfare
1-2-2, Kasumegaseki, Chiuoda-ku
Tokyo, 100
Japan

Dear Dr. Namba:

This is to acknowledge receipt of your letter concerning the importation of puffer fish into the United States and the summary of discussions which took place between the U.S. Food and Drug Administration and Mr. Hisanori Uchiyama of the Ministry of Health and Welfare, Japan, during the U.S.-Japan Food Chemical Panel Meeting, November 9 and 10, 1988 in Washington, D.C.

We concur with the procedures established and outlined in the summary of meeting which describes the actions the Japanese government will take to assure that the Food and Drug Administration's concerns regarding the safety of puffer fish are adequately addressed.

We look forward to continued cooperation between our two countries on issues of mutual interest.

Sincerely yours,

CFSAN Director is
currently Dr. Fred
Shank

Richard Ronk /s/
Acting Director
Center for Food Safety
and Applied Nutrition

Enclosure

Notes:

(Attachment)

For over a year, extensive discussions have been held between the United States Food and Drug Administration (FDA) and delegations from the Ministry of Health and Welfare (MHW), Japan concerning the importation of "Puffer fish" from Japan into the United States.

Puffer fish has been listed on FDA's Automatic Detention list since 1980 because the product "...appears to contain the poisonous and deleterious substance tetrodotoxin." FDA's concerns have been associated with the sampling of puffer fish and the analytical methodology to determine the absence or presence of tetrodotoxin. For unrestricted entry of puffer fish into the United States there is no adequate sampling scheme that can assure a safe lot since any single fish may contain a lethal dose of tetrodotoxin. While progress has been made in analytical methodology to determine the presence of toxin, it is still inadequate. These concerns are compounded by the fact that there is no known antidote for tetrodotoxin. The discussions with MHW officials were concerned with actions the Japanese government would take to assure that FDA's concerns would be adequately addressed, thus ensuring the safety of imported puffer fish.

Both parties discussed and agreed to an intention to permit the import of Japanese puffer fish on the basis of special occasions provided that each entry is inspected by the appropriate official of the Japanese government and certified as safe. In addition, both parties agreed on the following necessary conditions for the export of Japanese puffer fish to the United States.

Notes:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

February 7, 1989

Dr. Ko Namba
Director
Veterinary Sanitation Division
Environmental Health Bureau
Ministry of Health and Welfare
1-2-2, Kasumegaseki, Chiyoda-ku
Tokyo, 100
Japan

Dear Dr. Namba:

This is in regard to our previous correspondence concerning the exportation of puffer fish into the United States from Japan. In the attachment to my December 6, 1988 letter to you, there is a section which discusses the formation of a U.S. import organization.

We wish to inform you that, Mr. Nobuyoski Kursoka, President, of Wako International Corp., New York, New York, has presented himself as the head of this organization. He has established that he has the necessary experience and qualifications to follow the procedures outlined in our agreement.

Mr. Kureoka has stated that he will accept the responsibility for creating an inspection board as a non-profit corporation. That inspection board will meet the shipments at Kennedy airport, perform the inspections and maintain the inspection certificates from Japan for the time specified in our agreement.

I want to emphasize that our willingness to permit the importation of puffer fish into this country was predicated on a limited basis and on an agreement that the government of Japan would insure that these fish are properly processed and certified safe for consumption prior to exportation.

Notes:

Page 2- Dr Ko Namba

We will keep you informed of further developments concerning this matter as they occur.

Sincerely yours,

CFSAN Director is currently: Dr. Fred Shank

Richard J. Ronk
Acting Director
Center For Food Safety
and Applied Nutrition

cc: Mr. Nobuyoshi Kuracka
Wako International Corp.
P.O. Box 1785
FDR Station
New York, N.Y. 10022

Notes:

WAKO INTERNATIONAL CORP
RESTAURANT NIPPON
P.O. BOX 1785 FDR STATION
155 EAST 52ND STREET
New York, N.Y. 10150-1917
(212) 371-7555-6-7

October 22, 1988

Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

CFSAN Director is
currently: Dr. Fred
Shank

Attn: Mr. Richard J. Ronk
Acting Director
Center for Food and Applied Nutrition

Dear Mr. Ronk:

Our meeting on September 12 with you, members of your staff, and Mr. Shiraishi, the representative in Washington of Japan's Ministry of Health and Welfare, was an occasion that I shall remember for the rest of my life.

I am filled with a sense of admiration and deep gratitude to you for both the care and the courageousness with which you reached your recent decision regarding the importation of tora-fugu (tiger-puffer fish) into the United States. I have also learned much over the past four years from the meticulous process by which the staff members of your agency accumulated precise and logical information in elucidating the issues involved in your decision. And, finally, through this long process I learned the real meaning of "Fairness" in America.

Long ago, when I was an exchange student at Graduate school of Miami University in Ohio, I took a seminar in History of American frontier and learned that one of the key elements of the American frontier spirit was a sense of fairness. Subsequently, during the twenty-five years of pursuing my business affairs since I opened Restaurant Nippon in New York in 1963, I have often experienced other instances of "American fairness."

But my experience with you regarding the import of this unusual product from Japan has been extraordinary. Through my long and complicated communications with you and your staff over these four years, I was truly fortunate to have experienced remarkable fairness.

Notes:

Your willingness to examine new issues with an open, unprejudiced mind, and to reach your decisions through a positive and constructive attitude, have convinced me once again that the best virtues of the American frontier spirit are still alive.

I understand fully the issues confronting you and your feelings in dealing with the matter of permitting the importation of tora-fugu into America. In order to assure the safety and highest quality of this food-product, I have pledged to you my utmost cooperation. In developing the best possible method for carrying forward the import of tora-fugu, I shall work in close consultation with Dr. Namba, Mr. Shiraishi, and Mr. Minagawa of the Ministry of Health and Welfare of Japan. In New York, when the tora-fugu arrives at Kennedy Airport, I shall follow your directives in cooperating fully with the FDA inspectors in order to immediately certify the quality and condition of the fish, and I shall regularly present reports to you.

In introducing fugu to America, we hope to further appreciation in this country of the finest aspects of Japanese cuisine - culture, which has history of more than 3,000 years. It is thanks to your enlightened, historical decision and to the diligent efforts of your staff that we shall have the opportunity to do so. Out of our deepest sense of gratitude to you, we shall exert every effort to introduce a taste for fugu to Americans in the safest and most appropriate manner possible.

Your sincerely,

Wako International Corp

Nobuyoshi Kuraoka /s/
President

Notes:

GUIDANCE BY FDA
MEMBERSHIP QUALIFICATION FOR THE TORAFUGU BUYERS'
ASSOCIATION

(1) Membership Qualification

- (A) Past three consecutive years, each member restaurant must have passed health inspection of New York City of FDA.
- (B) Each member restaurant must be equipped adequately in freezing and refrigerating facilities.
- (C) Responsible chef must attend Fugu seminar (conducted by Torafugu Buyers' Association) at least once.
- (D) Fugu must be consumed within two months after date of purchase.
- (E) Member must purchase from only importers approved by FDA.
- (F) Member must display its certificate issued by association, visible to all customers in the restaurant.
- (G) Purchased fugu must be consumed in the restaurant. It is prohibited to transfer or sell to other place.

(2) Members of the association must strictly observe the regulation prescribed by the law. The law prohibits any member to import individually without formal procedure, as below.

(A) Frequency of import

Three times in each season (September through following March) and only for the special occasions.

(B) Importers

Permission granted only to the officially recognized establishment. (Kagoshima Sangyo Boeki Co., Inc., is the only one at present.)

(C) Part of the fugu allowed to import

- (a) Skin, Meat and Testicles of Torafugu.
- (b) Permission granted only to the Torafugu authorized facility of Torafugu Export Association in Shimonoseki city, Yamaguchi prefecture.
- (c) And only to those with safety certification by Shimonoseki city or Yamaguchi prefecture attached.
- (d) Customs clearance performed only at JFK International Airport, New York and have to received inspection by both of FDA and Torafugu Inspection Board.

The above conditions throughly understood, I hereby apply for my membership in your Association. My restaurant is adequately equipped

Notes:

and personnel highly qualified. It leaves no doubt as to my qualifications today and years to come. I pledge to be valuable member.

Date: _____ 1989

To: U.S. Food and Drug Administration
200 C. Street, S.W.
Washington, D.C. 20204

Name of Restaurant:

Address:

Torafugu Buyers' Association Inc.
C/o Wako International Corp.
P.O. Box 17865 FDR Station
155 East 52nd Street
New York, NY 10022
Representative:

(Owner or President)

